

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

APTALIS PHARMA US INC., and.,
APTALIS PHARMA CANADA ULC,

Plaintiffs,

V.

MYLAN PHARMACEUTICALS INC.,
and MYLAN INC.,

Defendants.

Civil Action No. 3:13-cv-04158-MLC-LHG

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**PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW IN
FURTHER SUPPORT OF PLAINTIFF APTALIS'S MOTION TO SEAL**

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INTRODUCTION

Pursuant to Local Civil Rule 5.3(c), Defendants/Counterclaim-Plaintiffs Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, “Mylan”) hereby submit Proposed Findings of Fact and Conclusions of Law in further support of Plaintiff Aptalis’s¹ Motion to Seal (ECF No. 192). Specifically, Mylan seeks to seal portions of the October 15, 2015 Letter from David E. De Lorenzi to the Honorable Mary L. Cooper, U.S.D.J. (ECF No. 191) (the “Letter”).

Local Civil Rule 5.3(c) places the burden of proof on the moving party as to why a motion to seal or otherwise restrict public access should be granted. Specifically, it requires a showing of:

- (1) the nature of the materials or proceedings at issue;
- (2) the legitimate private or public interest which warrants the relief sought;
- (3) the clearly defined and serious injury that would result if the relief sought is not granted; and
- (4) why a less restrictive alternative to the relief sought is not available.

Set forth below are the findings of fact and conclusions of law addressing each of the elements of Local Civil Rule 5.3(c). These findings of fact and conclusions of law support the granting of Aptalis’s Motion to Seal:

I. The Nature of the Materials or Proceedings at Issue

A. Findings of Fact

1.) The Letter contains and/or reflects information that Mylan has designated as “Highly Confidential—Attorneys’ Eyes Only” pursuant to the Discovery Confidentiality Order,

¹ Plaintiffs Aptalis Pharma US Inc. and Aptalis Pharma Canada ULC (collectively “Aptalis”).

entered by this Court on December 16, 2013 (ECF No. 34), or which must be treated as such under the DCO.

2.) The Confidential Material in particular contains and/or reflects highly proprietary information relating to the potential launch date of Mylan's Abbreviated New Drug Applications ("ANDA") products.

B. Conclusions of Law

3.) There exists in civil cases a common law public right of access to judicial proceedings and records. Goldstein v. Forbes (In re Cendant Corp.), 260 F.3d 183, 192 (3d Cir. 2001) (citing Littlejohn v. BIC Corp., 851 F.2d 673, 677-78 (3d Cir. 1988)). The party seeking to seal any part of a judicial record bears the burden of demonstrating that "the material is the kind of information that courts will protect." Miller v. Indiana Hosp., 16 F.3d 549, 551 (3d Cir. 1994) (quoting Publicker Indus., Inc. v. Cohen, 733 F.2d 1059, 1071 (3d Cir. 1984)).

4.) This Court has the power to seal where confidential information may be disclosed to the public. Fed. R. Civ. P. 26(c)(1)(G) allows the court to protect materials containing "trade secret[s] or other confidential research, development, or commercial information[.]" upon motion by a party, to prevent harm to a litigant's competitive standing in the marketplace. See Zenith Radio Corp. v. Matsushita Elec. Indus. Co., Ltd., 529 F. Supp. 866, 889-91 (E.D. Pa. 1981).

II. The Legitimate Private or Public Interest which Warrants the Relief Sought

A. Findings of Fact

5.) The Letter contains information that Mylan has designated as confidential and proprietary information.

6.) In-house counsel for Mylan has submitted a Declaration stating that Mylan has an interest in not publicly disclosing this information and rely on such information to advance its respective business strategies and to maintain a competitive advantage.

7.) Commercially sensitive and proprietary information, such as non-public information related to Mylan's confidential business information, from which competitors could identify Mylan's commercial interests embodies content which, if disclosed, might (and likely would) harm Mylan's competitive standing.

8.) Aptalis and Mylan – private parties – are in a patent dispute. Mylan has a legitimate interest in ensuring that its confidential and proprietary non-public information remains undisclosed. If this information were to become available, then Mylan's competitors could potentially (and likely would) use that information in the highly competitive pharmaceutical product marketplace.

B. Conclusions of Law

9.) Courts have recognized that the presumption of public access is not absolute and may be rebutted. Republic of the Philippines v. Westinghouse Elec. Corp., 949 F.2d 653, 662 (3d Cir. 1991). “Every court has supervisory power over its own records and files, and access has been denied where court files might have become a vehicle for improper purposes.” Littlejohn, 851 F.2d at 678 (quoting Nixon v. Warner Commc'ns, Inc., 435 U.S. 589, 598 (1978)).

10.) Courts may deny access to and seal a document when it encompasses business information that might harm a litigant's competitive standing. See Littlejohn, 851 F.2d at 678 (citations omitted).

11.) This Court has held that the inclusion of trade secrets and other confidential information in documents warrant the sealing of such documents. “A well-settled exception to

the right of access is the ‘protection of a party's interest in confidential commercial information, such as a trade secret, where there is a sufficient threat of irreparable harm.’” In re Gabapentin Patent Litig., 312 F. Supp. 2d 653, 664 (D.N.J. 2004) (citation omitted). “The presence of trade secrets or other confidential information weighs against public access and, accordingly, documents containing such information may be protected from disclosure.” Id. (citations omitted).

12.) Information included in an ANDA often consists of trade secrets, and federal law requires such information to remain confidential. See In re Gabapentin Patent Litig., 312 F. Supp. 2d at 667 n.7 (citing 21 C.F.R. § 314.430(b)-(d)). As such, a party’s confidential processes, chemical formulas and specifications, and research information should be sealed. Id. at 667-68.

III. The Clearly Defined and Serious Injury that Would Result if the Relief Sought Is Not Granted

A. Findings of Fact

13.) In light of its reference to, and disclosure of, non-public business information that is otherwise unavailable to third parties, the public disclosure of the confidential information in the Letter poses a substantial risk of harm to Mylan’s legitimate proprietary interests and competitive position.

14.) Disclosure of specific information related to Mylan’s business practices would permit competitors to develop business strategies to duplicate, undercut or otherwise counter Mylan’s commercial performance.

15.) Competitors would improperly benefit from the disclosure of Mylan’s non-public business information and would likely use the confidential information to enhance their market or negotiation positions.

B. Conclusions of Law

16.) This Court has discretion to balance the factors for and against access to court documents. See Pansy v. Borough of Stroudsburg, 23 F.3d 772, 781 (3d Cir. 1994).

17.) Protection of a party's interest in confidential commercial information, such as a trade secret, is a sufficient threat of irreparable harm, and is clearly defined as a serious injury. See Publiker, 733 F.2d at 1071.

IV. Why a Less Restrictive Alternative to the Relief Sought Is Not Available

A. Findings of Fact

18.) Mylan's request to seal the Letter is narrowly tailored to restrict access only to confidential and proprietary business information concerning the products that are the subject of Mylan's ANDA.

19.) The disclosure of this confidential, proprietary information would pose a financial and competitive risk to Mylan. Accordingly, the only way to protect Mylan's interests is to seal the Letter.

B. Conclusions of Law

20.) Under Local Civil Rule 5.3(c)(2), a party seeking to seal documents must meet the fourth prong that a no less restrictive alternative to the relief sought is available. See Securimetrix, Inc. v. Iridian Techs., Inc., No. 03-cv-04394, 2006 WL 827889, at *2 (D.N.J. Mar. 30, 2006).

21.) The sealing of confidential documents and information is an accepted practice in the District of New Jersey. See In re Gabapentin Patent Litig., 312 F. Supp. 2d 653.

Respectfully submitted,

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